SUMMARY OF THE ON-SITE ASSESSMENT COMMITTEE MEETING AUGUST 9, 2000

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Wednesday, August 9, 2000, at 1 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. William Ingersoll of the United States Navy. A list of action items resulting from this meeting is given in Attachment A. A list of participants is given in Attachment B. *The purposes of the meeting were to review On-site Assessment, Chapter 3 of the NELAC Standards, as adopted at the Sixth NELAC Annual Meeting (NELAC VI), to discuss membership issues, and to make preparation for the upcoming interim meeting (NELAC VII).*

INTRODUCTION

Several committee members joined the teleconference from the 2000 Waste Testing and Quality Assurance Symposium (WTQA 2000) in Arlington, Virginia. After all participants had assembled, Mr. Ingersoll called the meeting to order by welcoming the committee's new voting member, Mr. Alfredo Sotomayer of the Wisconsin Department of Natural Resources. Mr. Ingersoll also informed the committee that Ms. Barbara McCleary of the Delaware Department of Natural Resources had expressed an interest in working on Appendix A (Basic Training Standard). He suggested that the committee should put Ms. McCleary in touch with the Appendix A subcommittee consisting of Dr. Ken Jackson and Dr. Margo Hunt.

PREPARATION FOR NELAC VII

Mr. Ingersoll informed committee members that the committee has been assigned one half-day working session at the upcoming Sixth NELAC Interim Meeting (NELAC VIi). He asked for a headcount of committee members who will be attending the meeting. Five committee members indicated that they will attend NELAC VIi. Two committee members indicated that they will be unable to attend the meeting due to conflicts with the International Laboratory Accreditation Cooperation (ILAC) 2000 Conference being held the same week in Washington, DC. Two committee members were undecided due to fiscal and scheduling constraints. The committee did not know if a meeting day had already been assigned to them, but indicated that Wednesday, November 1, 2000, would be the most convenient day for most members to meet. It was suggested that the committee investigate teleconference options for members who cannot attend the meeting in person. Mr. Ingersoll indicated that he would contact Ms. Jeanne Hankins, NELAC Director, to see if the committee's meeting day has already been decided and to obtain information about teleconference options.

After moderate discussion and evaluation of the committee's most pressing issues, the committee set the following agenda for discussion at NELAC VI:

Appendix A (Basic Training Standard)

- Appendix B (Technical Training Standard and Critical Performance Criteria)
- Quality Systems (QS) Checklist Update
- Proposed changes to the On-site Assessment Standard (Chapter 3) (Tentative agenda item Although the committee will probably receive comments after the July 2000 NELAC Standards are posted on the NELAC Website, they may not receive these comments in time for discussion at NELAC VIi.)

APPENDIX B/TECHNICAL TRAINING FOR ASSESSORS

Mr. Ingersoll asked Mr. Jack Hall to familiarize Mr. Sotomayer with the development of Appendix B (Technical Training Standard and Critical Performance Criteria). Mr. Hall explained that the committee has decided to set a standard for technical courses and allow the training marketplace to develop those courses. The concept was presented at NELAC VI with a handout summarizing the proposed Appendices B-1 (Standards for Technical Training Courses for Assessors) and B-2 (Summary of Critical Performance Criteria for Regulated Methods). Mr. Hall noted that he had received some comments on Appendix B-1 immediately prior to NELAC VI, but had not had enough time to include them in the handout. Appendix B-1 has now been modified to incorporate comments received to date. Mr. Sotomayer asked whether many of those comments were related to the issue of hands-on experience for assessors. In response, Mr. Hall suggested that the hands-on experience issue would relate more closely to Appendix B-2. Mr. Ingersoll invited Mr. Sotomayer to participate in the Appendix B subcommittee. The subcommittee, consisting of Mr. Hall, Mr. Sotomayer, and Mr. Richard Sheibley, will be chaired by Mr. Hall.

Ms. Marlene Moore, participating in the teleconference from WTQA 2000, noted that she had spoken to the symposium's 2001 planning committee and to two instrument manufacturers regarding the development of technical training courses for assessors. Ms. Moore noted that, although both Perkin-Elmer and Tekmar-Dohrmann representatives had expressed an interest in technical training, the environmental market is not their strong market. She suggested that one approach to successfully soliciting their assistance in technical training for assessors would be to remind them that the pharmaceutical industry may also be moving toward International Standards Organization (ISO) 17025-type systems and requirements. Ms. Moore indicated that Hewlett-Packard would also probably be interested in technical training development. She agreed to pass the pertinent contact information along to the Appendix B subcommittee.

It was suggested that Appendix B should follow ILAC outlines on establishing training courses, such as the ILAC 1994 G3 guidance document, *Guidelines for Training Courses for Assessors*, which was electronically distributed to committee members on February 18, 2000 by Ms. Susan Davis of the City of Austin. Ms. Mimi Uhlfelder volunteered to redistribute the document for new committee members and members who might have misplaced it.

CURRENT STATUS OF NELAC ASSESSMENTS/ASSESSOR TRAINING

Ms. Moore informed the committee that she had heard numerous comments at WTQA 2000 about NELAC. As a result of NELAC, laboratories have noted consistency in their on-site assessments and a reduction in the number of assessments. However, laboratories do not feel that state assessors have been adequately trained. Laboratories are looking for improvement in the assessor bank and want to know what they can expect from future assessor training. Ms. Moore anticipated that the committee would be faced with similar comments and questions at NELAC VIi.

Discussion turned to the question of whether the National Environmental Laboratory Accreditation Program (NELAP) assessments are consistent with the NELAC Standards. Committee members representing regulated laboratories recounted their recent experiences with NELAP audits, citing several deviations from the NELAC Standards. After considerable discussion, the committee identified three major issues associated with reported evidence of assessor deficiencies:

- Assessors must receive adequate training.
- Assessors need refresher training within the next year.
- Accrediting authorities (AAs) must ensure that their assessors are following the NELAC Standards.

The committee was in agreement that, although it is not within the committee's scope to single out assessors for criticism, it is within the committee's scope to address these issues. The committee urged those members who had had recent NELAP assessments to report assessor deficiencies through proper NELAC channels so that these problems will be made known to Ms. Hankins, the NELAC Board of Directors (BoD), and the AA Workgroup. It was noted that every member of the On-site Assessment Committee would benefit from accompanying an assessor on an on-site assessment. It was suggested that members assemble for a face-to-face committee meeting to assess a laboratory working on or toward the NELAP process. The committee agreed that they would need to obtain the permission of the laboratory beforehand and suggested laboratories that might be willing to put themselves through the process. Since no resolution was reached in subsequent discussion, the issue was tabled.

There was considerable discussion of refresher training for assessors. Committee members were uncertain of whether the issue of refresher training to ensure consistency in interpretation of the NELAC Standards is a separate issue from the consistency issues discussed earlier in the teleconference. It was suggested that the assessor deficiency issues discussed earlier are much bigger than just inconsistency in interpretation of the NELAC Standards. The committee was in agreement that unless there is some mechanism to cross-calibrate assessors to the NELAC Standards, assessors are going to take divergent paths. It was agreed that it is important that the people who attend NELAC meetings have the authority to make policy decisions. It was also agreed that it is equally important that these people take information from the NELAC meetings back to their assessors. In discussion of possible mechanisms for offering annual refresher training, the committee revisited much of the discussion from

their July 12, 2000 teleconference. For reference, the pertinent section of the July 12 minutes is given in Attachment C. The following additional suggestions were made concerning how an annual refresher course or assessor forum might be offered to assessors:

- Satellite conferencing system
- Video presentation
- Assessor forum at national NELAC meetings (also addressed in July 12 meeting)
- Regional assessor meetings (also addressed in July 12 meeting)

Since the committee failed to reach a consensus on refresher training or assessor forums, the issue was tabled for discussion at a future meeting.

UPDATE OF QS CHECKLIST

Mr. Charles Dyer reported that he has almost completed the update of the microbiology section of the Quality Systems (QS) checklist. He is incorporating the newly revised NELAC QS Standard but is not incorporating ISO 17025. The work to incorporate ISO 17025 into the NELAC Standards is outside the On-site Assessment Committee. Mr. Dyer will complete the sections on which he is working and then hand off to Ms. Uhlfelder. Mr. Dyer and Ms. Uhlfelder hope to have completed the checklist by the committee's next teleconference.

CONCLUSION

The allotted time for the teleconference having expired, the meeting was adjourned at 2:30 p.m. EDT. The committee's next meeting is scheduled for August 23, 2000, at 1:00 p.m. EDT via teleconference.

ACTION ITEMS ON-SITE ASSESSMENT COMMITTEE MEETING AUGUST 9, 2000

Item No.	Action	Responsible Member	Date to be Completed
1.	Committee will refer Barbara McCleary to Appendix A subcommittee.	W. Ingersoll	Immediately
2.	Committee will contact Jeanne Hankins re NELAC VIi meeting day and teleconference.	W. Ingersoll	Immediately
3.	Appendix B subcommittee will include Alfredo Sotomayer and will coordinate on development of Appendices B-1 and B-2.	J. Hall R. Sheibley A. Sotomayer	Immediately
4.	Marlene Moore will pass along contact information for instrument manufacturers to Appendix B subcommittee	M. Moore	Immediately
5.	Mimi Uhlfelder will distribute ILAC guidance document on training courses for assessors to committee members.	M. Uhlfelder	Complete
6.	Committee will review ILAC guidance document on training courses for assessors.	All	8/23/00

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DISCUSSION OF NELAC ASSESSOR FORUM FROM JULY 12, 2000 ON-SITE ASSESSMENT COMMITTEE MEETING

Develop Process to Communicate Standard Clarification and Explanation -

The committee discussed ways in which stakeholders might ensure the nationally consistent interpretation and implementation of the NELAC Standards by NELAC assessors. It was suggested that NELAC adopt a process similar to that used by EPA's Office of Compliance for Good Laboratory Practices (GLPs) in which a numbered Regulation Advisory is issued whenever clarification is needed. The Regulation Advisory, with supporting documentation attached, sets a precedent for future users. An alternate suggestion was that an assessor forum be held at regular intervals so that NELAC assessors can get input from other assessors and arrive at some consensus opinion. It was generally agreed that consensus interpretation of the NELAC Standards would be the most practical means of clarification. It was also generally agreed that forum minutes documenting the consensus interpretation, perhaps in question and answer format, could then be referenced by assessors unable to attend the forum. There was extensive committee discussion and brainstorming of how such a forum might be implemented. Suggestions for implementation of a NELAC assessor forum, together with the potential stumbling block identified for each, are summarized as follows:

Suggestion 1 - Assessor forum attached to NELAC meetings

Potential Stumbling Block - A significant number of assessors do not attend NELAC

meetings.

Suggestion 2 - Electronic forum on NELAC Website

Potential Stumbling Block - Many opinions, no resolution

Suggestion 3 - Continuing education requirements for assessors to include

attendance at a NELAC assessor forum every four years

Potential Stumbling Block - Four years too long between forums

Suggestion 4 - Annual regional forums for NELAC assessors

Potential Stumbling Block - Too much work for NELAC committees hosting the forums

Suggestion 5 - NELAC-sponsored assessor forum attached to annual Waste

Testing and Quality Assurance (WTQA) Symposium as a double-incentive for assessor attendance (consensus-building

forum and technical training)

Potential Stumbling Block - WTQA instructors must be amenable to modifying courses to

fit NELAC requirements